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09/628,472	07/31/2000	Paul K. Wolber	10003511-1	5543	
22878 7590 08/15/2007 AGILENT TECHNOLOGIES INC. INTELLECTUAL PROPERTY ADMINISTRATION, LEGAL DEPT.			EXAMINER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)				
		09/628,472	WOLBER ET AL.				
	Office Action Summary	Examiner	Art Unit				
		BJ Forman	1634				
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Status	•						
1)	Responsive to communication(s) filed on						
- '=		 action is non-final.					
3)	Since this application is in condition for allowa		prosecution as to the merits is				
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Disposit	ion of Claims						
4)⊠	Claim(s) 1-15 and 21-23 is/are pending in the	application.	•				
٠,,٣	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	5) Claim(s) is/are allowed.						
7)	Claim(s) is/are objected to.		•				
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·=	The specification is objected to by the Examine The drawing(s) filed on is/are: a)☐ acc		the Everiner				
10)	Applicant may not request that any objection to the		•				
	Replacement drawing sheet(s) including the correct		• •				
11)	The oath or declaration is objected to by the Ex						
	ınder 35 U.S.C. § 119						
	Acknowledgment is made of a claim for foreign	nriarity under 25 LLC C S 14	0(a) (d) as (f)				
	☐ All b)☐ Some * c)☐ None of:	priority under 33 0.3.0. § 11	5(a)-(u) 01 (1).				
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	 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 						
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	r No(s)/Mail Date	6) Other:	• •				

DETAILED ACTION

Status of the Claims

1. This action is in response a Decision by the Board of Appeals and Interferences. The Board affirmed the rejections of Claims 1-9, 21-23. The Board reversed the rejection of Claims 10-15. The previous rejections of Claims 1-9, 21-23 in the Final Office Action dated 3 June 2004 are maintained and reiterated below. New grounds for rejection for Claims 10-15 are discussed.

Claims 1-9, 21-23 stand rejected by the Board of Appeals and Interferences.. Claims 10-15 are rejected.

New Grounds for Rejection

Based on Prior Art cited in the Decision of the Board of Appeal and Interferences

4. Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dattagupta et al (U.S. Patent No. 4,734,363, issued 29 March 1988) and Conrad (U.S. Patent No. 5,652,099, issued 29 July 1997) as applied to Claim 1 and further in view of Sgroi et al (Cancer Research, 1999, 59: 5656-5661) and/or Schena et al (PNAS, 1996, 93: 10614-10619)

Regarding Claim 10, Dattagupta et al teach a method for producing a mixture of nucleic acid comprising providing distinct single-stranded nucleic acids immobilized on a substrate wherein the nucleic acid comprises a constant domain at the 3' end (complement to #16, Fig. 1) and a variable region at the 5' end (complement to #20, Fig. 1), hybridizing a nucleic acid (#16) to the constant domain to produce a duplex having a double-stranded region and a single-stranded variable-region overhang, subjecting the duplex to cyclic reactions to produce a

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linearly amplified single-stranded nucleic acids and separating the single-stranded nucleic acids (Column 1, line 65-Column 2, line 58 and Examples 1, 5 and 6).

Conrad teaches a method for producing a mixture of nucleic acids the method comprising providing a plurality of different-sequence single-stranded nucleic acids, each comprising a constant domain at the 3' end (e.g. M13 primer site (fig. 14) and/or T7/SP6 promoter sites (fig. 23)) and a variable domain at the 5' end (i.e. vector insert and/or gene template) hybridizing nucleic acids to the constant domain to produce a duplex having a double-stranded region and a single-stranded variable-region overhang and subjecting the duplex to cyclic reactions to produce a mixture of linearly-amplified single stranded nucleic acids of differing sequences (i.e. probe cocktail)(Example 2, Column 24, line 53-Column 26, line 3).

Dattagupta et al does not teach the immobilized nucleic acids have differing sequences. However, as detailed above, Conrad teaches the similar method using nucleic acids of differing sequences whereby a "cocktail of probes" is produced for detection of different length, different number and/or different location of targets. Conrad further teaches these three different types diagnostic targets illustrate the broad importance of the probe cocktail producing (Column 28, lines 50-58). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe synthesis of Dattagupta et al by immobilizing additional nucleic acids of different sequences for the expected benefit of proving various types of diagnostics based and further based on the broad importance of probe cocktails as taught by Conrad (Column 28, lines 50-58).

Conrad does not teach immobilized duplexes. However, as detailed above, Dattagupta et al (A) teach the similar method wherein the duplexes are covalently immobilized (Fig. 1). Dattagupta et al teaches their immobilized duplexes provide large-scale production of sequence-specific probes while eliminating the need for plasmids, cloning and restriction (Column 1, lines 31-35). It would have been obvious to one of ordinary skill in the art at the

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time the claimed invention was made to modify the probe synthesis of Conrad by immobilizing their plurality of duplexes for the expected benefit of providing large scale production of sequence-specific probes as taught by Dattagupta et al (A) (Column 1, lines 31-35).

Dattagupta et al and Conrad do not teach using their nucleic acids as primers to make a population of target nucleic acids. However, as noted by the Board, the instant specification acknowledges that "Gene expression analysis protocol are well known to those of skill intehr art, and the population of target nucleic acids produced by the subject methods find use in many, if not all, of these protocols." (page 15, last paragraph).

The Board further stated:

First, we have already concluded that the step of generating a mixture of nucleic acids according to the method of claim 1 is obvious over the combination of Dattagupta '363 and Conrad. Second, claims 10 and 13 appear to be drawn to steps that are used in gene expression analysis, discussed in the background of the invention, and, as noted by Appellants at page 15 of the Specification, "[g]ene expression analysis protocols are well known to those of skill in the art, and the populations of target nucleic acids produced by the subject methods find uses in many, if not all, of these protocols."

As an example of such a protocol, we point the Examiner's and Appellants' attention to Schena et al. ("Parallel human genome analysis: Microarray-based expression monitoring of 1000 genes," Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 10614-10619 (1996)) and Srgoi et al. ("In Vivo Gene Expression Profile Analysis of Human Cancer Progression," Cancer Research, Vol. 59, pp. 5656-5661 (1999)).

Schena describes a gene expression analysis protocol, in which cDNA is made from mRNA using two probes (which reads on a mixture of nucleic acids, which could be generated using the method of claim 1). Schena also uses a micro array to detect the presence of target nucleic acids hybridized to probe nucleic acids of said array.

Sgroi teaches a method of gene expression profile analysis, in which mRNA was reverse transcribed using random hexamers (which reads on a mixture of nucleic acids, which could have been generated by the method of claim 1), and also teaches the use of a microarray to detect the presence of target nucleic acids hybridized to probe nucleic acids of said array.

Regarding Claim 10, Sgroi et al teach a method for making a population of targets, employing a mixture of nucleic acids as primers to produce targets from mRNA (page 5656-5657).

Regarding Claim 11, Sgori et al teach the method wherein the target generation step comprises template driven primer extension (RTQ-PCR, page 5657).

Regarding Claim 12, Sgori teaches the method wherein said target generation step produces labeled target nucleic acids (RTQ-PCR, page 5657).

Regarding Claim 13, Sgori teaches the method further comprising a hybridization assay comprising contacting the generated targets of Claim 10 with immobilized targets and detecting (page 5657-5658).

Regarding Claim 14, Sgori teaches the method wherein the targets are labeled (RTQ-PCR, page 5657).

Regarding Claim 15, Sgori teaches their method further comprises washing the surface of the array (page 5655-56-57).

The method steps of primer extension using mRNA templates to produce labeled targets and hybridization of the targets to an array were well known in the art at the time the claimed invention was made. And by Applicant's own admission, use of labeled targets from mRNA templates for gene expression analysis was well known in the art.

Hence, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the targets generated using the combined teaching of Dattagupta and Conrad in the method of gene expression analysis of Sgori.

REITERATED FROM PREVIOUS OFFICE ACTION AS AFFIRMED BY THE BOARD

OF APPEALS AND INTERFERENES

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 1-9 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dattagupta et al. (U.S. Patent No. 4,734,363, issued 29 March 1988) and Conrad (U.S. Patent No. 5,652,099, issued 29 July 1997).

Regarding Claim 1, Dattagupta et al teach a method for producing a mixture of nucleic acid comprising providing distinct single-stranded nucleic acids immobilized on a substrate wherein the nucleic acid comprises a constant domain at the 3' end (complement to #16, Fig. 1) and a variable region at the 5' end (complement to #20, Fig. 1), hybridizing a nucleic acid (#16) to the constant domain to produce a duplex having a double-stranded region and a single-stranded variable-region overhang, subjecting the duplex to cyclic reactions to produce a linearly amplified single-stranded nucleic acids and separating the single-stranded nucleic acids (Column 1, line 65-Column 2, line 58 and Examples 1, 5 and 6).

Conrad teaches a method for producing a mixture of nucleic acids the method comprising providing a plurality of different-sequence single-stranded nucleic acids, each comprising a constant domain at the 3' end (e.g. M13 primer site (fig. 14) and/or T7/SP6 promoter sites (fig. 23)) and a variable domain at the 5' end (i.e. vector insert and/or gene template) hybridizing nucleic acids to the constant domain to produce a duplex having a double-stranded region and a single-stranded variable-region overhang and subjecting the duplex to cyclic reactions to produce a mixture of linearly-amplified single stranded nucleic acids of differing sequences (i.e. probe cocktail)(Example 2, Column 24, line 53-Column 26, line 3).

Dattagupta et al does not teach the immobilized nucleic acids have differing sequences. However, as detailed above, Conrad teaches the similar method using nucleic acids of differing sequences whereby a "cocktail of probes" is produced for detection of different length, different number and/or different location of targets. Conrad further teaches these three different types diagnostic targets illustrate the broad importance of the probe cocktail producing (Column 28, lines 50-58). It would have been obvious to one of ordinary skill in the art at the

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time the claimed invention was made to modify the probe synthesis of Dattagupta et al by immobilizing additional nucleic acids of different sequences for the expected benefit of proving various types of diagnostics based and further based on the broad importance of probe cocktails as taught by Conrad (Column 28, lines 50-58).

Conrad does not teach immobilized duplexes. However, as detailed above, Dattagupta et al teach the similar method wherein the duplexes are covalently immobilized (Fig. 1).

Dattagupta et al teaches their immobilized duplexes provide large-scale production of sequence-specific probes while eliminating the need for plasmids, cloning and restriction (Column 1, lines 31-35). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe synthesis of Conrad by immobilizing their plurality of duplexes for the expected benefit of providing large scale production of sequence-specific probes as taught by Dattagupta et al (Column 1, lines 31-35).

Hence the instantly claimed invention is obvious over Dattagupta et al in view of Conrad or alternatively over Conrad in view of Dattagupta et al.

Regarding Claim 2, Dattagupta et al teaches the method wherein the nucleic acids produced are DNA (Column 2, lines 34-54). Conrad teaches the nucleic acids produces are DNA (Column 24, lines 53-56).

Regarding Claim 3, Dattagupta et al teaches the method wherein the constant domain comprises a recognition domain (e.g. complement of #16, Fig. 1) and a linker domain (Column 2, lines 24-32). Conrad teaches the method wherein the constant domain comprises a recognition domain (e.g. M13 primer site (fig. 14) and/or T7/SP6 promoter sites (fig. 23).

Regarding Claim 4, Dattagupta et al teaches the method wherein the cycling is linear amplification (fig. 1 and Column 2, lines 34-54). Conrad teaches the method wherein the cycling is linear i.e. asymmetric synthesis (Column 24, lines 53-67).

Regarding Claim 5, Dattagupta et al teach a method for producing a mixture of nucleic acid comprising providing distinct single-stranded nucleic acids immobilized on a substrate

wherein the nucleic acid has L (linker, Column 2, line 24-34)-R (e.g. complement of #16, Fig. 1)-F (e.g. complement for 3'nt of the primer whereby the polymerase extends) and a variable region at the 5' end (complement to #20, Fig. 1), hybridizing a nucleic acid (#16) to the R-F domains to produce a duplex having a double-stranded region and a single-stranded variable-region overhang, subjecting the duplex to cyclic reactions to produce a linearly amplified single-stranded nucleic acids and separating the single-stranded nucleic acids (Column 1, line 65-Column 2, line 58 and Examples 1, 5 and 6).

Conrad teaches a method for producing a mixture of nucleic acids the method comprising providing a plurality of different-sequence single-stranded nucleic acids, each comprising a R (primer complement)- F (polymerase binding site) (e.g. M13 primer site (fig. 14) and/or T7/SP6 promoter sites (fig. 23)) and a variable domain at the 5' end (i.e. vector insert and/or gene template) hybridizing nucleic acids to the constant domain to produce a duplex having a double-stranded region and a single-stranded variable-region overhang and subjecting the duplex to cyclic reactions to produce a mixture of linearly-amplified single stranded nucleic acids of differing sequences (i.e. probe cocktail)(Example 2, Column 24, line 53-Column 26, line 3).

Dattagupta et al does not teach the immobilized nucleic acids have differing sequences. However, as detailed above, Conrad teaches the similar method using nucleic acids of differing sequences whereby a "cocktail of probes" is produced for detection of different length, different number and/or different location of targets. Conrad further teaches these three different types diagnostic targets illustrate the broad importance of the probe cocktail producing (Column 28, lines 50-58). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe synthesis of Dattagupta et al by immobilizing additional nucleic acids of different sequences for the expected benefit of proving various types of diagnostics based and further based on the broad importance of probe cocktails as taught by Conrad (Column 28, lines 50-58).

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Conrad does not teach immobilized duplexes. However, as detailed above, Dattagupta et al teach the similar method wherein the duplexes are covalently immobilized (Fig. 1).

Dattagupta et al teaches their immobilized duplexes provide large-scale production of sequence-specific probes while eliminating the need for plasmids, cloning and restriction (Column 1, lines 31-35). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe synthesis of Conrad by immobilizing their plurality of duplexes for the expected benefit of providing large scale production of sequence-specific probes as taught by Dattagupta et al (Column 1, lines 31-35).

Hence the instantly claimed invention is obvious over Dattagupta et al in view of Conrad or alternatively over Conrad in view of Dattagupta et al.

Regarding Claim 6, Dattagupta et al teaches the method wherein the linker domain is 0-10 bases (Column 2, lines 24-33). Conrad teaches the method wherein the linker domain is 0 bases (Example 2).

Regarding Claim 7, Conrad teaches the method wherein the functional domain is RNA polymerase promoter domain (Column 25, lines 35-40).

Regarding Claim 8, Dattagupta et al teaches the method wherein the recognition domain is recognized by a restriction enzyme (Column 3, lines 1-17). Conrad teaches the method wherein the recognition domain is recognized by a restriction enzyme (e.g. *Eco R1*, Fig. 14 and Example 2).

Regarding Claim 9, Dattagupta et al teaches the method wherein the cycling is linear amplification (fig. 1 and Column 2, lines 34-54). Conrad teaches the method wherein the cycling is linear i.e. asymmetric synthesis (Column 24, lines 53-67).

Regarding Claims 21 and 22, Dattagupta et al teach a method for producing a mixture of nucleic acid comprising providing distinct single-stranded nucleic acids immobilized on a substrate wherein the nucleic acid comprises a constant domain at the 3' end (complement to #16, Fig. 1) and a variable region at the 5' end (complement to #20, Fig. 1), hybridizing a

nucleic acid (#16) to the constant domain to produce a duplex having a double-stranded region and a single-stranded variable-region overhang, subjecting the duplex to cyclic reactions to produce a linearly amplified single-stranded nucleic acids and separating the single-stranded nucleic acids (Column 1, line 65-Column 2, line 58 and Examples 1, 5 and 6).

Conrad teaches a method for producing a mixture of nucleic acids the method comprising providing a plurality of different-sequence single-stranded nucleic acids, each comprising a constant domain at the 3' end (e.g. M13 primer site (fig. 14) and/or T7/SP6 promoter sites (fig. 23)) and a variable domain at the 5' end (i.e. vector insert and/or gene template) hybridizing nucleic acids to the constant domain to produce a duplex having a double-stranded region and a single-stranded variable-region overhang and subjecting the duplex to cyclic reactions to produce a mixture of linearly-amplified single stranded nucleic acids of differing sequences (i.e. probe cocktail)(Example 2, Column 24, line 53-Column 26, line 3).

Dattagupta et al does not teach the immobilized nucleic acids have differing sequences. However, as detailed above, Conrad teaches the similar method using nucleic acids of differing sequences whereby a "cocktail of probes" is produced for detection of different length, different number and/or different location of targets. Conrad further teaches these three different types diagnostic targets illustrate the broad importance of the probe cocktail producing (Column 28, lines 50-58). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe synthesis of Dattagupta et al by immobilizing additional nucleic acids of different sequences for the expected benefit of proving various types of diagnostics based and further based on the broad importance of probe cocktails as taught by Conrad (Column 28, lines 50-58).

Conrad does not teach immobilized duplexes. However, as detailed above, Dattagupta et al teach the similar method wherein the duplexes are covalently immobilized (Fig. 1).

Dattagupta et al teaches their immobilized duplexes provide large-scale production of

sequence-specific probes while eliminating the need for plasmids, cloning and restriction (Column 1, lines 31-35). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe synthesis of Conrad by immobilizing their plurality of duplexes for the expected benefit of providing large scale production of sequence-specific probes as taught by Dattagupta et al (Column 1, lines 31-35).

Dattagupta et al teaches subjecting the duplexes to in vitro transcription (reverse transcription) or linear amplification (Fig. 1 and Column 2, lines 41-48). Conrad teaches subjecting the duplexes to in vitro transcription (T7 transcription) or linear amplification (asymmetric) (Column 24, lines 53-56).

Hence the instantly claimed invention is obvious over Dattagupta et al in view of Conrad or alternatively over Conrad in view of Dattagupta et al.

Claim 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dattagupta (A) (U.S. Patent No. 4,734,363, issued 29 March 1988) and Conrad (U.S. Patent No. 5,652,099, issued 29 July 1997) in view of Dattagupta (B) (U.S. Patent No. 5,215,899, issued 1 June 1993).

Regarding Claim 23, Dattagupta et al teach a method for producing a mixture of nucleic acid comprising providing distinct single-stranded nucleic acids immobilized on a substrate wherein the nucleic acid comprises a constant domain at the 3' end (complement to #16, Fig. 1) and a variable region at the 5' end (complement to #20, Fig. 1), hybridizing a nucleic acid (#16) to the constant domain to produce a duplex having a double-stranded region and a single-stranded variable-region overhang, subjecting the duplex to cyclic reactions to produce a linearly amplified single-stranded nucleic acids and separating the single-stranded nucleic acids (Column 1, line 65-Column 2, line 58 and Examples 1, 5 and 6).

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Conrad teaches a method for producing a mixture of nucleic acids the method comprising providing a plurality of different-sequence single-stranded nucleic acids, each comprising a constant domain at the 3' end (e.g. M13 primer site (fig. 14) and/or T7/SP6 promoter sites (fig. 23)) and a variable domain at the 5' end (i.e. vector insert and/or gene template) hybridizing nucleic acids to the constant domain to produce a duplex having a double-stranded region and a single-stranded variable-region overhang and subjecting the duplex to cyclic reactions to produce a mixture of linearly-amplified single stranded nucleic acids of differing sequences (i.e. probe cocktail)(Example 2, Column 24, line 53-Column 26, line 3).

Dattagupta et al does not teach the immobilized nucleic acids have differing sequences. However, as detailed above, Conrad teaches the similar method using nucleic acids of differing sequences whereby a "cocktail of probes" is produced for detection of different length, different number and/or different location of targets. Conrad further teaches these three different types diagnostic targets illustrate the broad importance of the probe cocktail producing (Column 28, lines 50-58). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe synthesis of Dattagupta et al by immobilizing additional nucleic acids of different sequences for the expected benefit of proving various types of diagnostics based and further based on the broad importance of probe cocktails as taught by Conrad (Column 28, lines 50-58).

Conrad does not teach immobilized duplexes. However, as detailed above, Dattagupta et al teach the similar method wherein the duplexes are covalently immobilized (Fig. 1).

Dattagupta et al teaches their immobilized duplexes provide large-scale production of sequence-specific probes while eliminating the need for plasmids, cloning and restriction (Column 1, lines 31-35). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe synthesis of Conrad by immobilizing

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their plurality of duplexes for the expected benefit of providing large scale production of sequence-specific probes as taught by Dattagupta et al (Column 1, lines 31-35).

Dattagupta (A) and Conrad both teach linear amplification but they do not teach strand-displacement amplification. However, Dattagupta (B) teaches a similar method for producing single stranded nucleic acids wherein the preferred method of linear amplification is strand displacement whereby multiple cycles of amplification are provided (Column 9, lines 58-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the strand displacement of Dattagupta (B) to the linear amplification of Dattagupta (A) and Conrad based on the preferred teaching of Dattagupta (A)(Column 9, lines 58-67).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D. Primary Examiner Art Unit: 1634 August 13, 2007